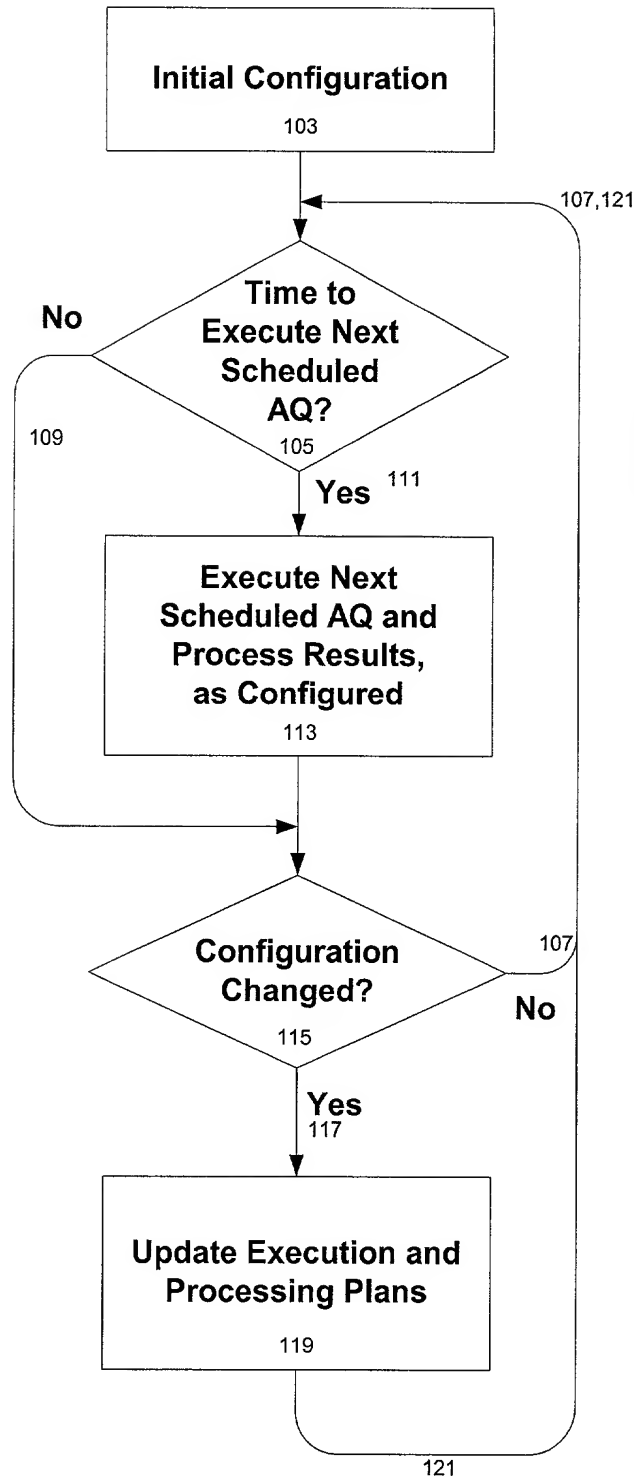


103: The **Initial Configuration** is used to define the execution and processing plans, including the following:

- **Query (search / trigger criteria)**
- **Admin Scope**
- **Admin Schedule**
- **Admin Activity**
- **Admin Query**

113: In this step the next scheduled **Admin Query**, is executed, querying the database, searching for records meeting the given **Admin Query** conditions, and processing all PRs in the **Result Set**.

119: Upon detection of changes in the execution and, or the processing plans, the system adopts the new plans and is ready to continue with the next cycle



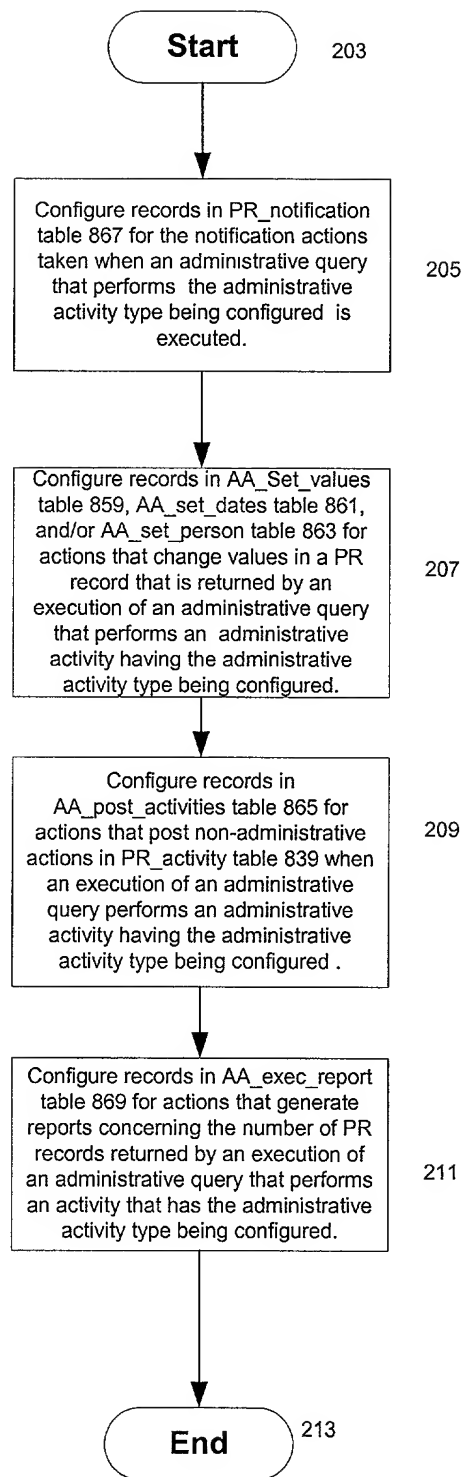
105: In this step the next Admin Query, if any, is executed, querying the database, searching for records meeting the given **Admin Query** conditions.

115: A periodical check for whether the current execution plan and process plan have changed, e.g.,

- Removal of exiting **AQs**.
- Changes in Admin Schedule.
- Changes in Admin Scope (adding or removing Projects, i.e., work areas).
- New Admin Activities.
- New Notification Rules.

FIG. 1

FIG. 2



201

FIG. 2

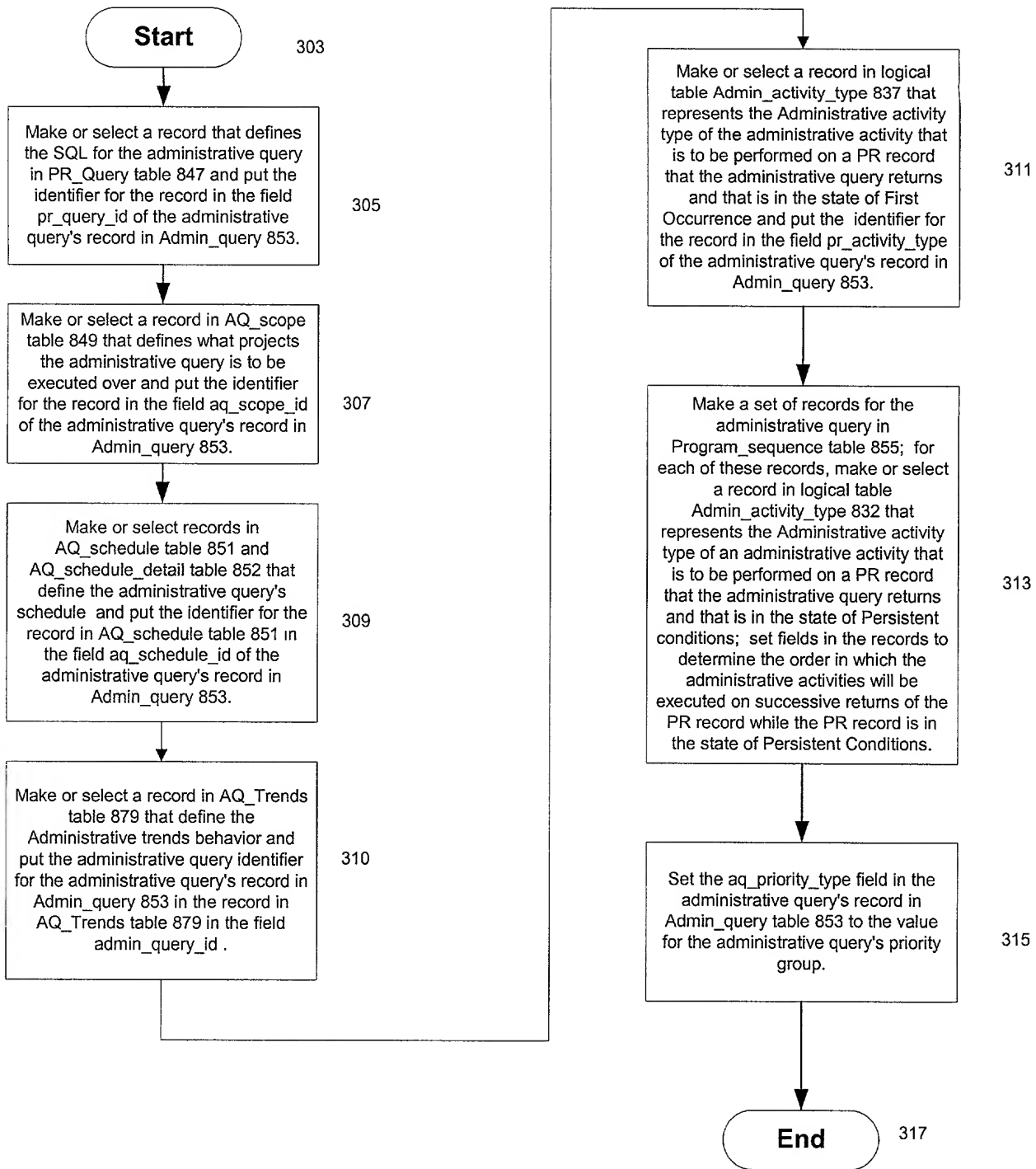
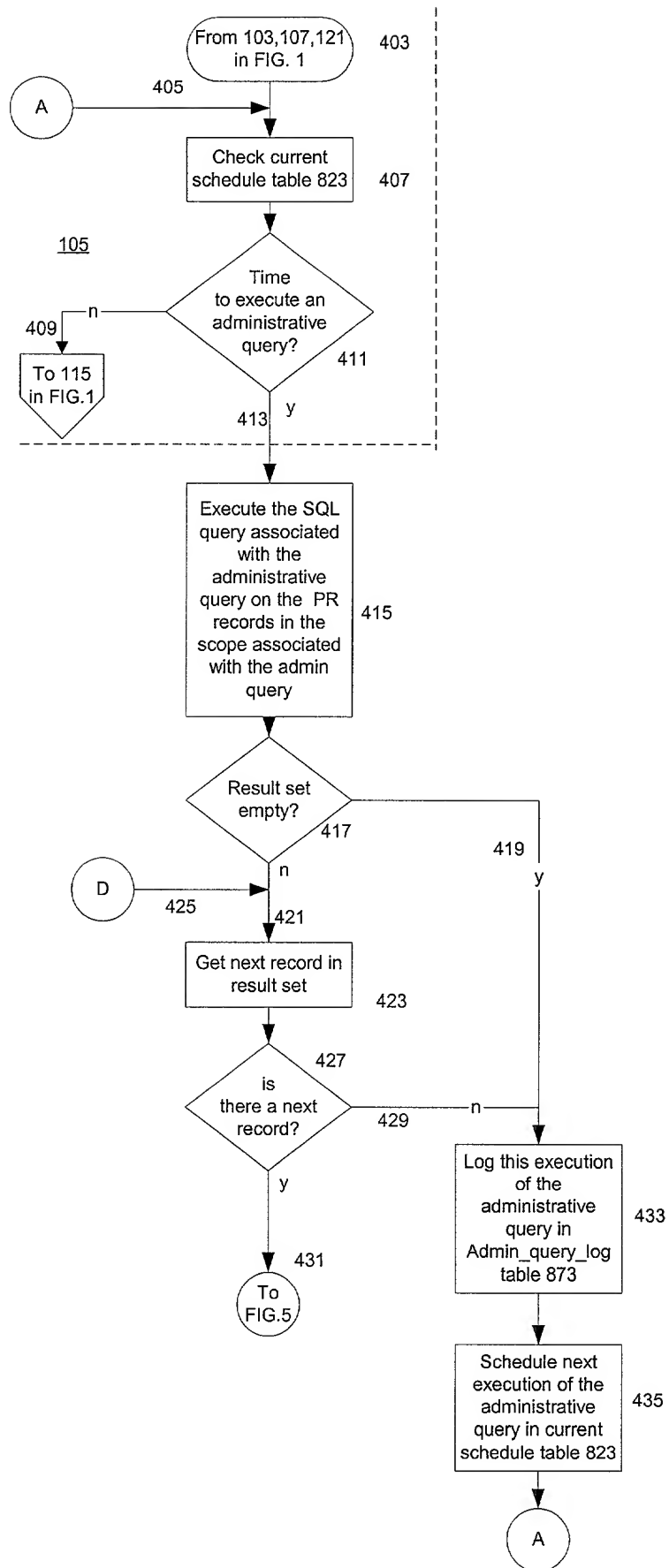
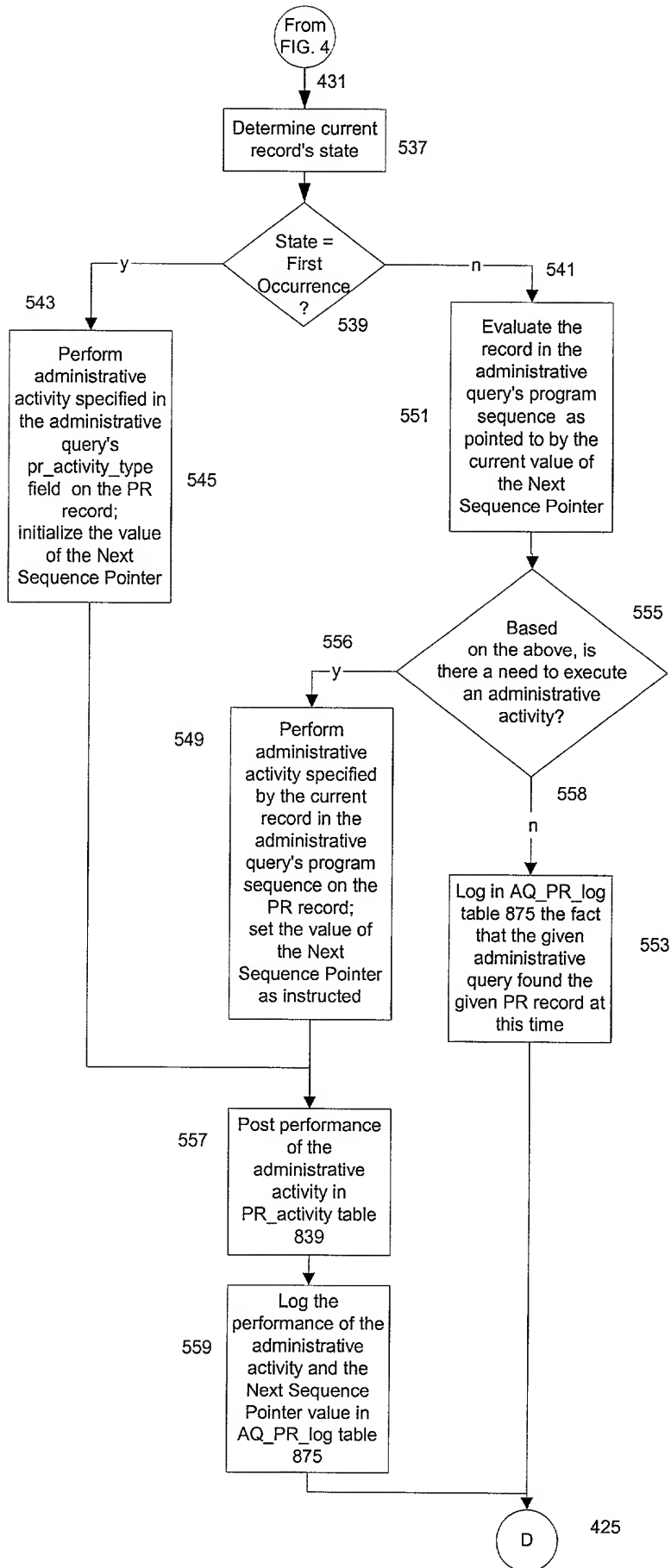


FIG. 3



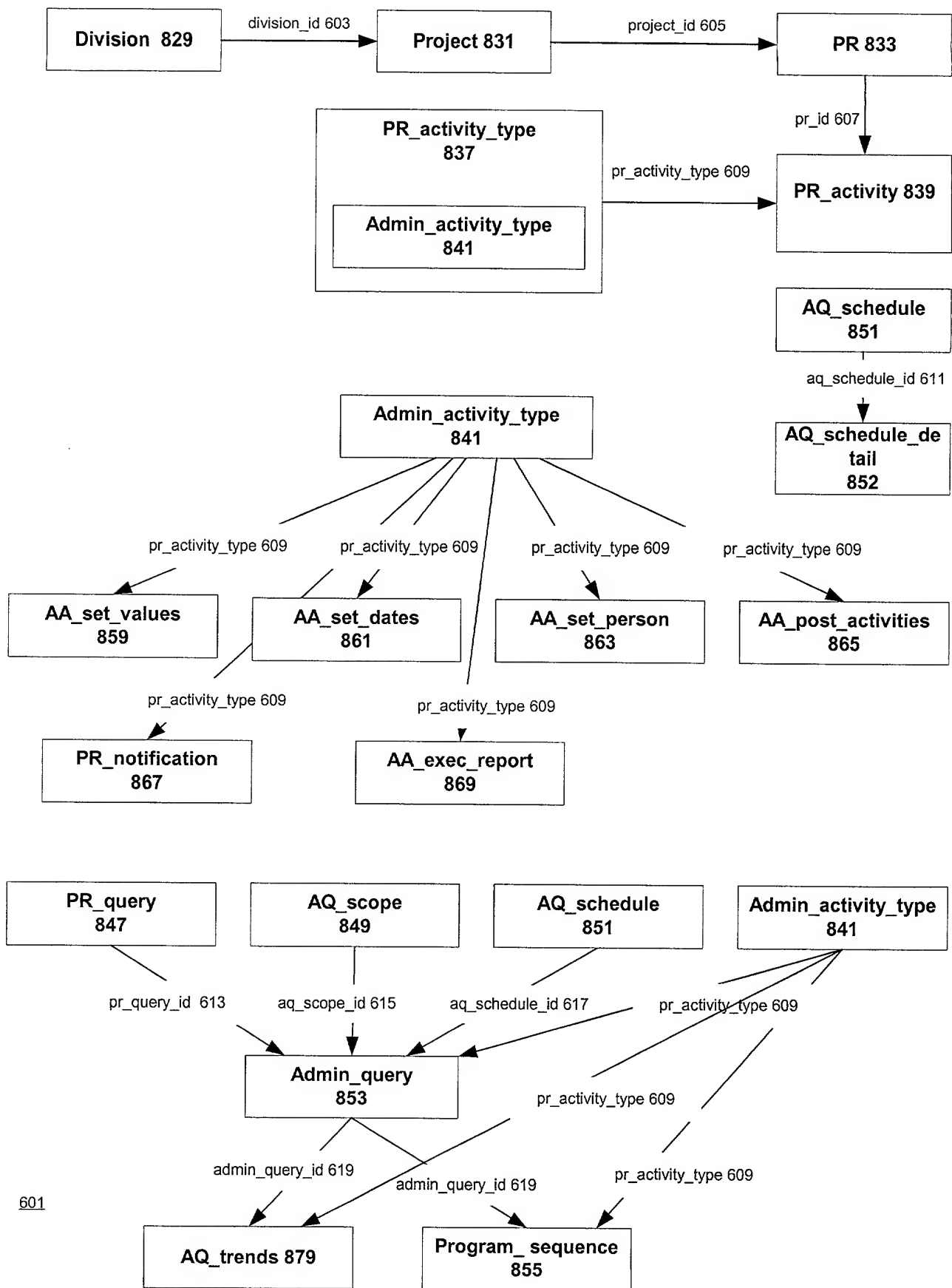
401

FIG. 4



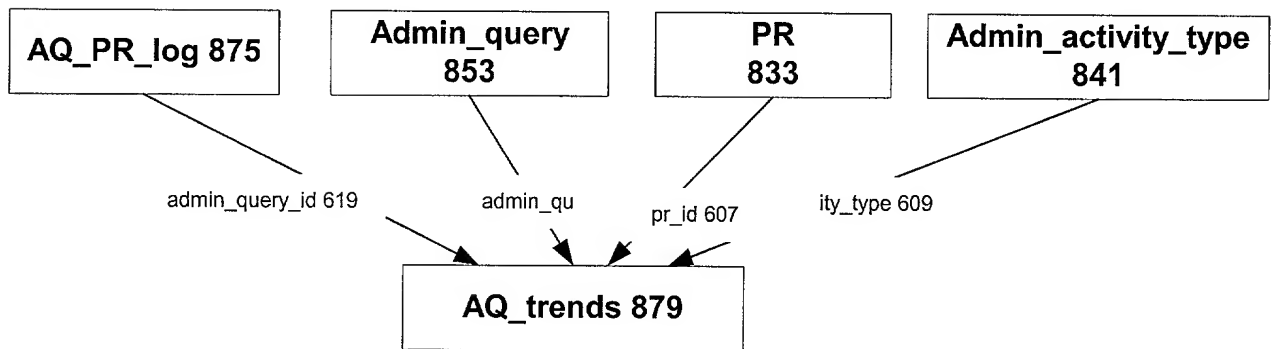
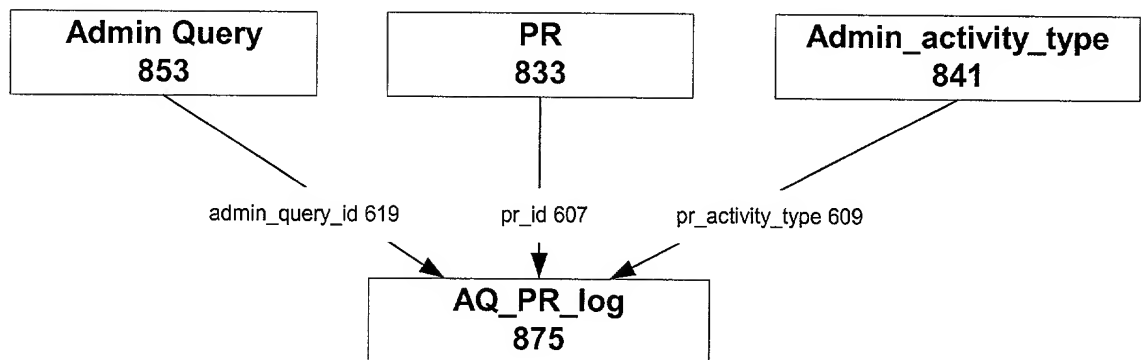
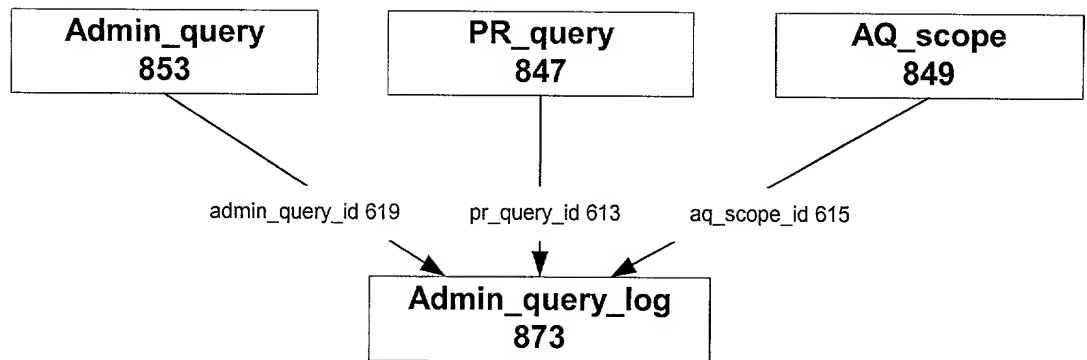
501

FIG. 5



601

FIG. 6



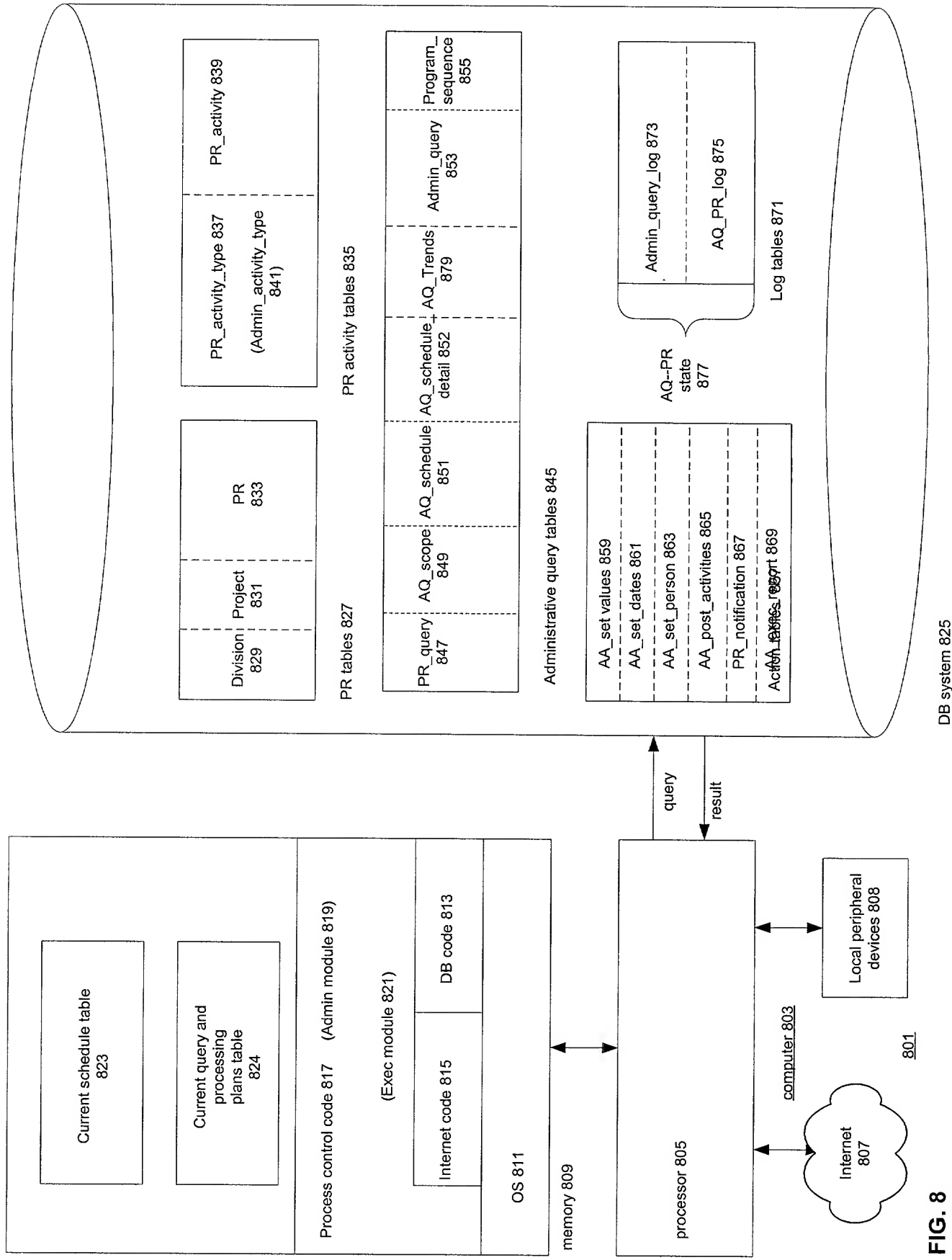


FIG. 8

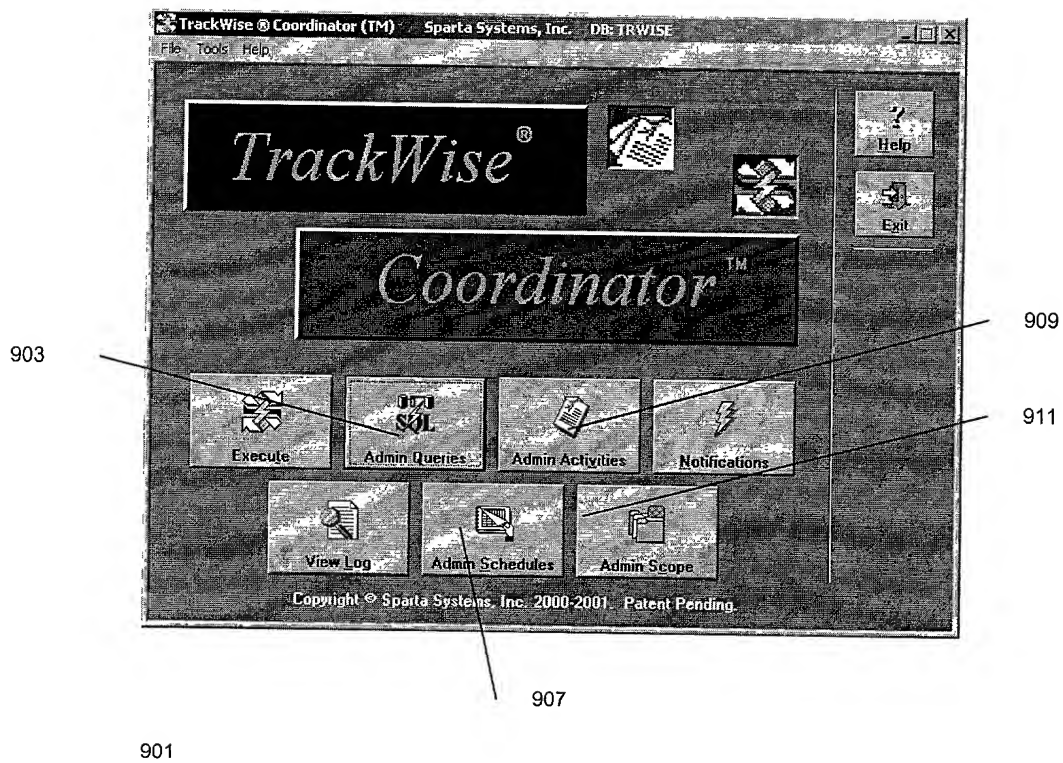
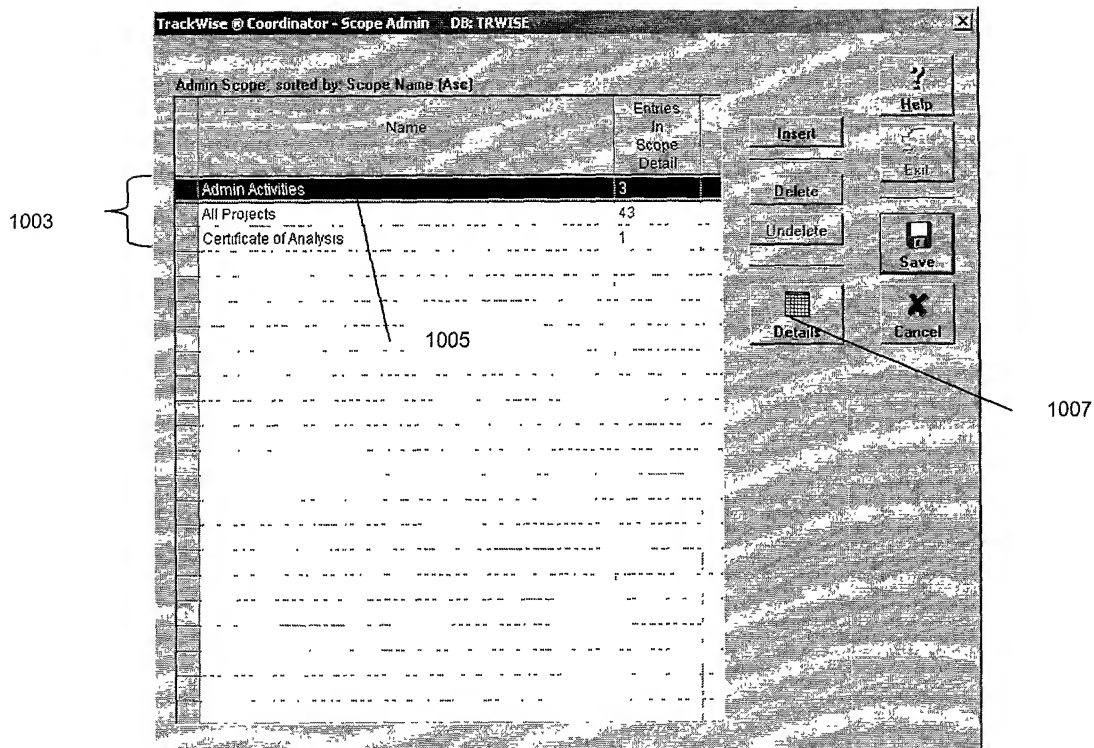


FIG. 9



1001

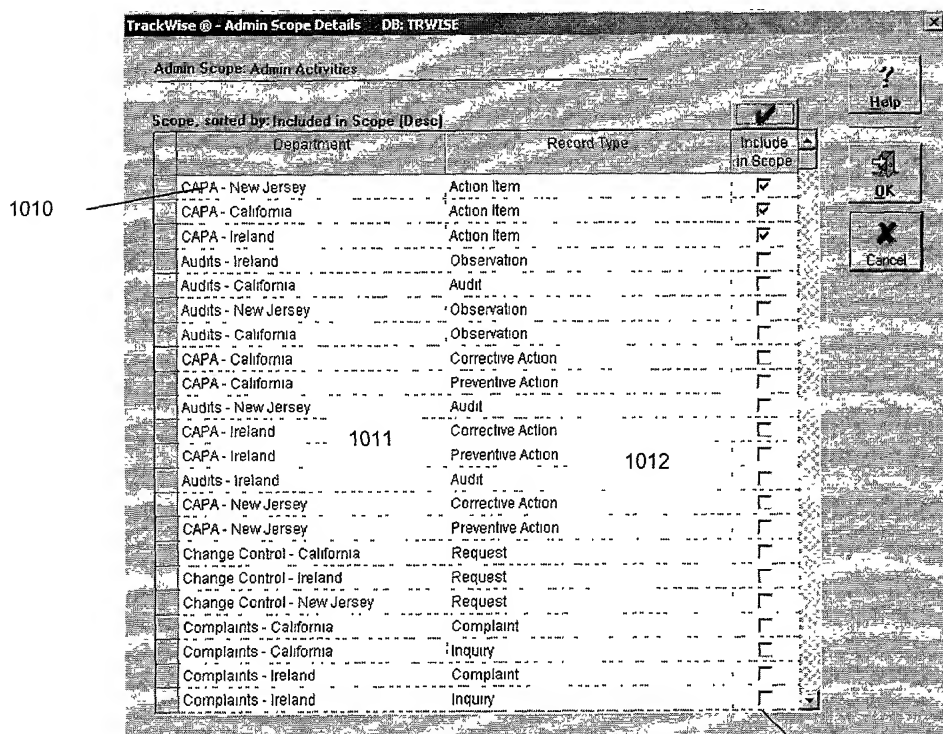


FIG. 10

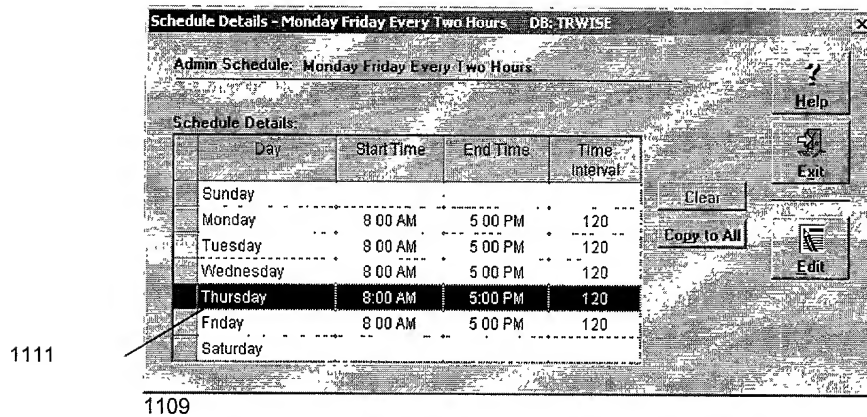
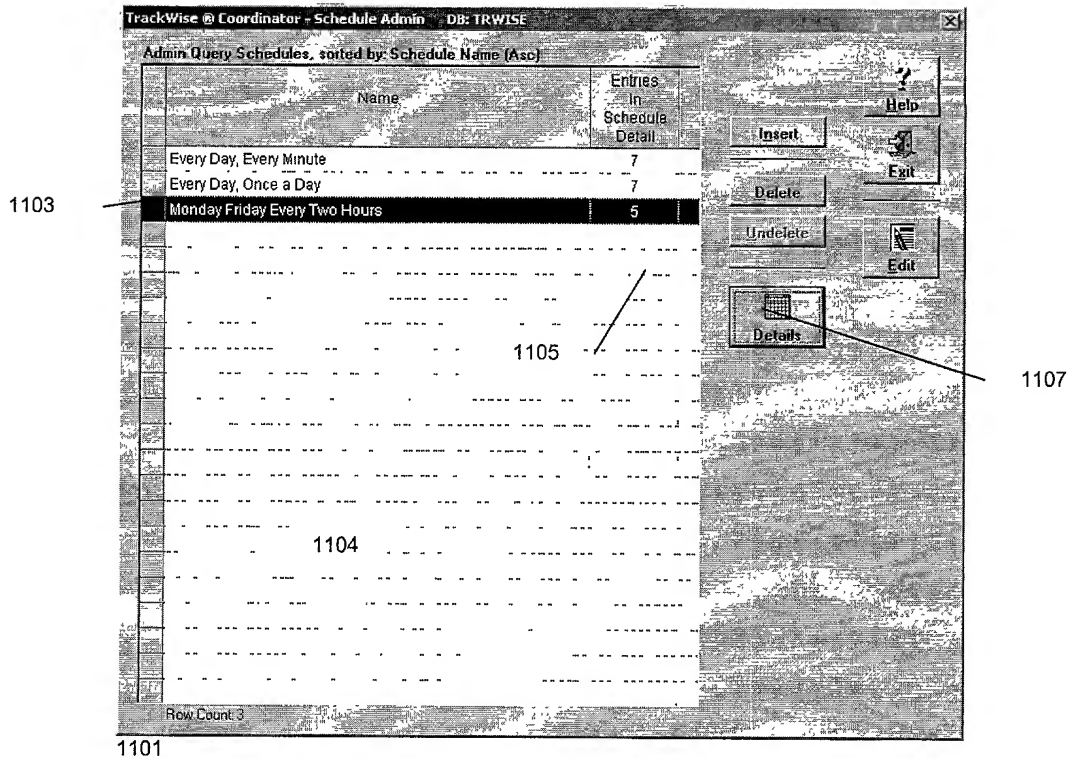


FIG. 11

1215
1217
1219
1221

TrackWise Coordinator - Admin Activity Maintenance DB:TRWISE

Admin Activities Only All Activity Types

Admin Activities, sorted by Admin Activity Name (Asc)

Admin Activity Name	Sets Values?	Sets Dates?	Sets Persons?	Posting Activities?
Assigned To Notification	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Emergency Priority-Date Due Setting	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Low Priority-Date Due Setting	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Normal Priority-Date Due Setting	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Post Begin Audit Activity	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RNH 8279 Lower Limit Alert	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RNH 8279 Upper Limit Alert	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RNH 8280 Upper Limit Alert	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RNH 8281 Upper Limit Alert	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RNH 8282 Upper Limit Alert	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Set Assigned To	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Set Priority to Emergency	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Unassigned Record	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Unassigned Record Notification	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Row Count: 14

1203

1205

1207 1209 1211 1213

FIG. 12

Administration of Setting Selection Values

Admin Activity: Set Priority to Emergency

Set values, sorted by Field Name (Asc)

Field Name to Set	Field Type	Operation	Set Values
Additional Samples Tested?	Selection		
Affected SOP	Selection		
Assessment Method	Selection		
Assignable Cause	Multi-Selection		
Condition	Selection		
Disposition of Samples	Selection		
Final Disposition	Selection		
Governing SOP	Selection		
Impact	Selection		
Location	Selection		
Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection		
Product(s)	Multi-Selection		
Proposed Disposition	Selection		
Type	Selection		

1303 1305 1307 1309

1301

1306

Mfg Stage	Selection	
Phase	Selection	
Priority	Selection	Set Emergency
Product Family	Selection	
Product(s)	Multi-Selection	Increment 1311
Proposed Disposition	Selection	Set
Type	Selection	Clear

1310

Selection Values DB: TRWISE

Emergency

Low

Normal

1313

Help

Ok

Cancel

FIG 13

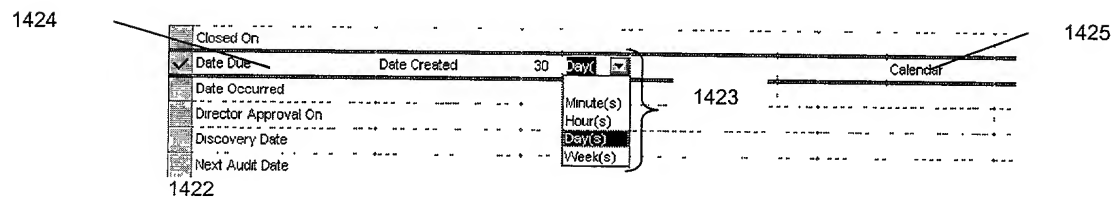
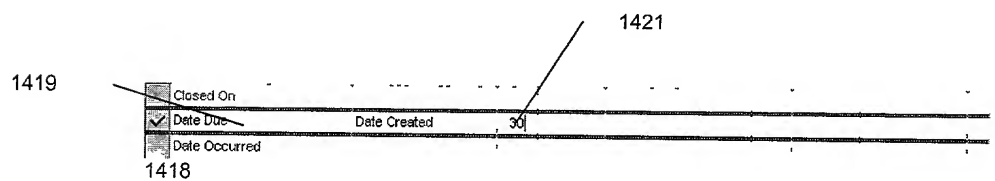
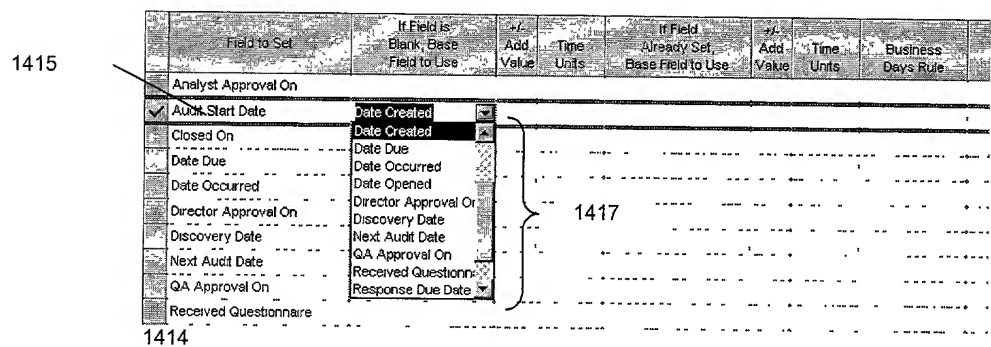
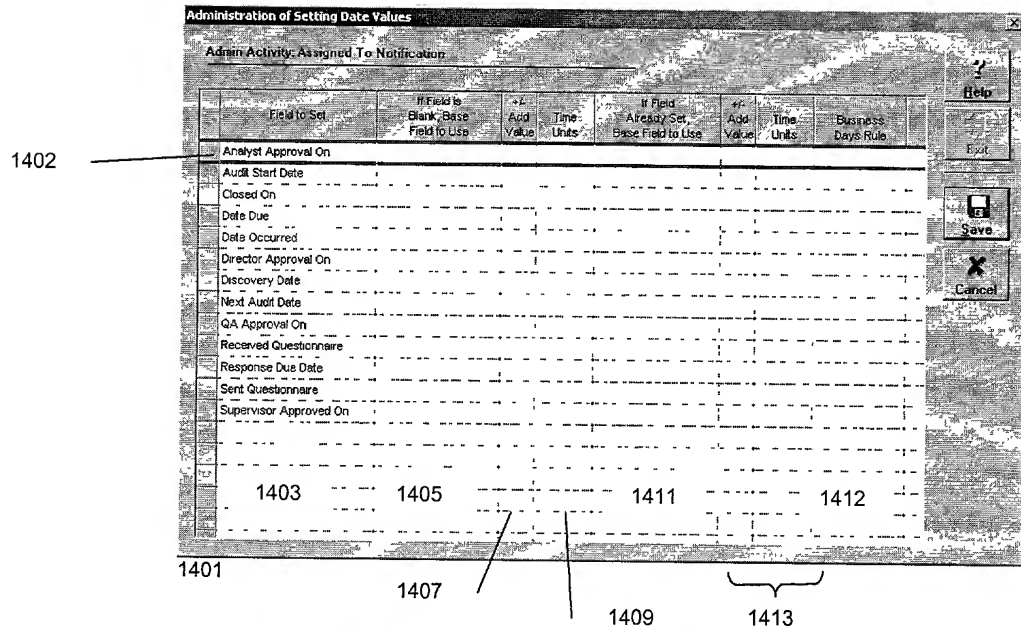


FIG. 14

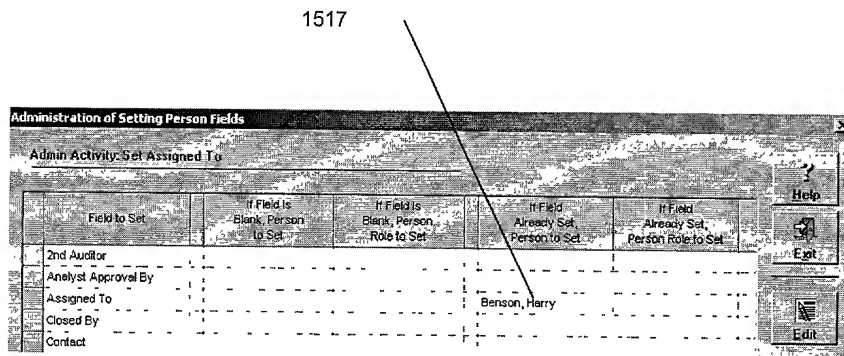
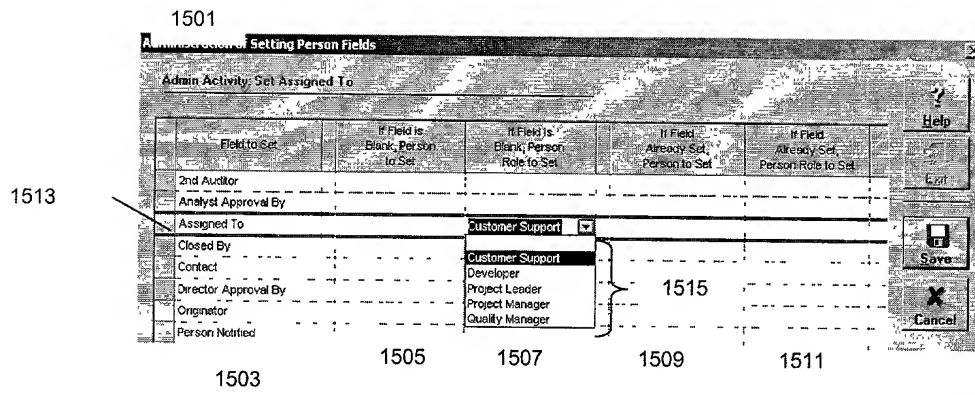


FIG. 15

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
✓ Begin Audit	Perform						
Begin Change Control	Schedule						
Begin Investigation	Perform						
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							

Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.

1602

1601

1604

1603

1605

1609

1611

1607

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
✓ Begin Audit	Schedule	Current Date/Time	2	Day(s)	Calendar		
Begin Change Control							
Begin Investigation							
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							

Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.

1613

1614

1615

FIG. 16

TrackWise ® - Admin Query Maintenance DB: TRWISE

Active Admin Queries: Query Name (Asc)

Query Name	Triggered Activity	Admin Scope	Schedule	Priority Group	Program Entries
Emergency Priority	Emergency Priority-Date Due Setting	Admin Activities	Monday Friday Every Two Hours	2	1
Low Priority	Low Priority Date Due Setting	Admin Activities	Monday Friday Every Two Hours	2	1
Normal Priority	Normal Priority-Date Due Setting	Admin Activities	Monday Friday Every Two Hours	2	1
Over Due Records	Assigned To Notification	All Projects	Every Day, Every Minute	2	1
RNH 6279 <3 5	RNH 6279 Lower Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6279 >4 5	RNH 6279 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6380 > 8	RNH 6280 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6381 >5 5	RNH 6281 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6382 >1 6	RNH 6282 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
Unassigned PRs	Unassigned Record	Admin Activities	Monday Friday Every Two Hours	2	2

Row Count: 10

1702

1703 1705 1707 1709

1701

1712

1714

1717

1719

1711

1713

Program Sequence Details DB: TRWISE

Admin Query: Unassigned PRs

Program Sequence, sorted by: Sequence Number (Asc) (no other sorting is available)

Seq. No.	Triggered Activity	Program Control: What to do after Executing the Current Sequence	Time Interval (in minutes)
1	Unassigned Record Notification Next - Advance to next sequence (wait given time interval)		120
2	Unassigned Record Notification Next - Advance to next sequence (wait given time interval)		60
3	Unassigned Record Notification Continue - Continue forever (wait given time interval)		30

1723

1727 1729 1731

1721

1725

FIG. 17

FIG. 18 Prior Art

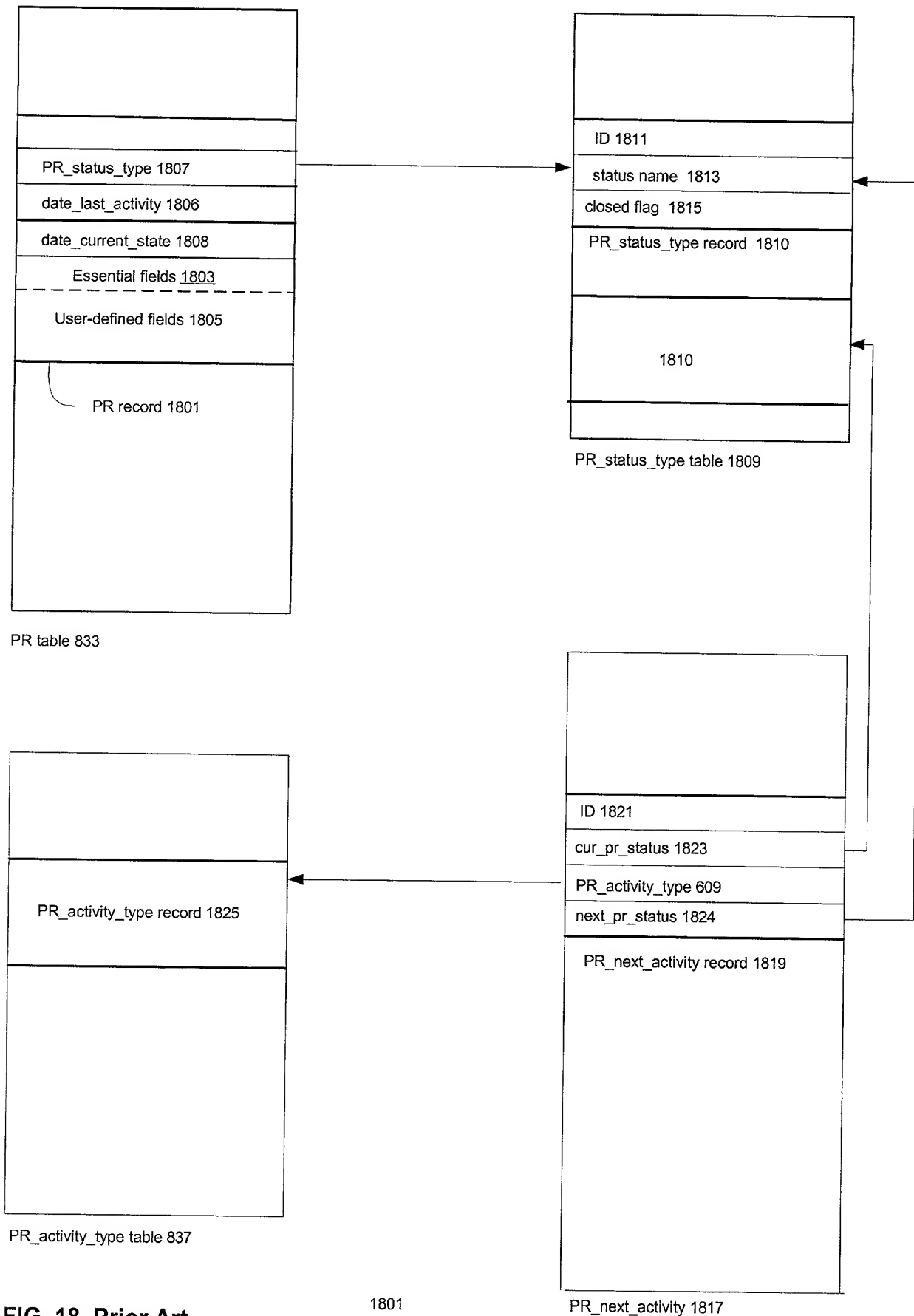


FIG. 18 Prior Art

1801

PR_next_activity 1817

TrackWise® - Activity Type Administration DB: TESTBASE

Search by Letter: Sorted by: Name (Asc)

Activity Type

Activity Type	2007	2009	Can Schedule	Min Participants	Can Edit All Data	Can Edit Summary only
Activity A	Activity A	Activity A	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Activity B	Activity B	Activity B	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Activity C	Activity C	Activity C	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Additional Work	Additional Work	Additional Work	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Approve Closed - No Action	Approve Closed - N	Approve Closed - N	<input checked="" type="checkbox"/>	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Approve Work	Approve Work	Approve Work	<input type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Back to Initiated	Back to Initiated	Back to Initiated	<input type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Back to Work In Progress	Back to WIP	Back to WIP	<input type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Begin Work	Begin Work	Begin Work	<input type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Call Vendor	Call Vendor	Call Vendor	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Row Count: 59

When Selected Activity is Performed:

☐ Require Electronic

☐ Require a person to be responsible for this Activity

☐ Require summary

Set Date/Time UDF with Date Performed: Date/Time Approved

Set Person UDF with the Person that Performed the Activity: The Approver

Schedule the Following Activity: 2023

Number of Days After Date Performed:

Summary Prompt: Completed Prompt: Scheduled Prompt: (120 ch's max)

2025

Buttons: Help, Insert, Delete, Undelete, Save, Cancel, Changing (Projects), Report

2001

FIG. 20